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ABSTRACT

The education of students in the techniques of critical appraisal of drug studies has been identified as a deficiency in many health sciences curricula. Errors in research design and inconsistencies in the reporting of study results persist in professional pharmacy and medical journals. Thus, thorough and accurate review and interpretation of journal studies are essential for assuring that patients receive proper drug therapy. This project developed an interactive, computer instructional program that would teach students to evaluate all aspects of published drug efficacy studies. The content for the program was identified, prepared, and designed for an interactive computer format, and the program was developed using "Authorware Professional." The program, "Evaluation of Clinical Drug Studies," consists of 10 main sections with several subsections. Two consecutive classes of pharmacy students at West Virginia University tested the program, which was found to increase significantly their knowledge of critical drug study evaluation techniques compared to a control group and pretests. Appendices include the timetable for the project; "Development and Evaluation of a Computer-Assisted Instructional Program To Teach Critical Evaluation of Drug Studies" (Marie A. Abate, Arthur I. Jacknowitz, James M. Shumway, and Anne H. Nardi)--an article published in "American Journal of Pharmaceutical Education," Volume 57, Winter 1993; computer program evaluation summary for 1994; and information for FIPSE. (SWC)

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ED 416 823

# Cover Sheet - Final Report

**Development of a Computer System to Educate Students to Evaluate and Interpret Published Drug Studies**

Grantee Organization:
West Virginia University
School of Pharmacy
P.O. Box 9520
Morgantown, WV 26506-9520

Grant Number: P116B10076

Project Dates:
Starting Date: September 1, 1991
Ending Date: December 31, 1994 (includes 6 month extension from original ending date of August 31, 1994)

Project Director:
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FIPSE Program Officer: David Johnson

Grant Award:

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|---|---|
| Year 1: | $ 51,405 |
| Year 2: | $ 38,148 |
| Year 3: | $ 29,382 |
| | $ 6,945 (supplemental award) |
| | $ 125,880 |

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**Summary**

The education of students in the techniques of critical appraisal of drug studies has been identified as a deficiency in many health sciences curricula. Errors in research design and inconsistencies in the reporting of study results persist in professional pharmacy and medical journals. Thus, thorough and accurate review and interpretation of journal studies are essential for assuring that patients receive proper drug therapy. The objective of this project was to develop an interactive, computer instructional program that would teach students to evaluate all aspects of published drug efficacy studies. The content for the program was identified, prepared, and designed for an interactive computer format, and the program was developed using Authorware Professional®. The program, "Evaluation of Clinical Drug Studies," consists of 10 main sections with several subsections. Two consecutive classes of pharmacy students tested the program, which was found to increase significantly their knowledge of critical drug study evaluation techniques compared to a control group and pretests. The computer program has recently been converted into an IBM Windows format, in addition to the original Macintosh format. Plans are currently underway to distribute the program to interested schools and colleges of pharmacy and medicine, health care practitioners, and pharmaceutical industry professionals.

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The "Evaluation of Clinical Drug Studies" program received one of the "Innovations in Teaching" awards from the American Association of Colleges of Pharmacy in 1993.

Results from program testing were published:
Abate MA, Jacknowitz AI, Shumway JM, Nardi AH. Development and Evaluation of a Computer-Assisted Instructional Program to Teach Critical Evaluation of Drug Studies. *Am J Pharm Educ* 1993;57:416-424.

The "Evaluation of Clinical Drug Studies" program received U.S. copyright registration in August, 1994.

# Executive Summary
# Development of a Computer System to Educate Students to Evaluate and Interpret Published Drug Studies

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## Project Overview

A computer instructional program was developed to teach health professions students to critically analyze and interpret published drug efficacy studies. An initial version of the program, "Evaluation of Clinical Drug Studies," was developed over a 16 month period for use on the Macintosh computer. It was evaluated by second professional year pharmacy students at WVU during two consecutive years (1993 and 1994). The program was found to significantly increase students' knowledge of drug study evaluation concepts and to improve their ability to critically evaluate published efficacy studies. Overall, students felt that the program was of high quality and useful in increasing their subject knowledge. An IBM compatible Windows version of the program is currently being completed. The most appropriate avenue(s) to use for program dissemination are being identified and should be initiated shortly.

## Purpose

The idea to develop a computer instructional program to teach critical evaluation of published drug studies arose due to a number of factors. First, the importance of literature evaluation skills was well known to the investigators, two of whom are drug information specialists. Second, computer assisted instruction was incorporated into pharmacy school curricula to only a limited extent nationwide. However, the flexibility and portability of computer assisted instruction, combined with its student centered learning focus, made it desirable to develop. Third, although a number of checklists, scoring systems and algorithms were published to assist health care providers in evaluating clinical studies, they were generally brief and did not adequately explain the concepts contained. Finally, pharmacy students at WVU received a required one credit hour course in drug literature, but the course focused on texts and not journal articles. This, combined with the investigators' interest in computers and instructional methods, led to the idea of developing a comprehensive computer program to teach the critical analysis of drug efficacy studies.

Pitfalls encountered with the development and use of the computer program include the following. It required a considerable amount of time to learn how to use Authorware Professional™, more than originally anticipated. An instructional designer should also be available to anyone who initiates a project such as this. Adequate time must be allowed to identify the area(s) of the curriculum in which to utilize such a computer program. Finally, adequate equipment and private work areas must be available for student use.

## Background and Origins

Computer assisted instruction was used infrequently at the West Virginia University Schools of Pharmacy and Medicine prior to initiation of this project. Another curricular deficiency was that the students did not receive any formal education in drug literature evaluation techniques, although the need for such education has been increasingly called for in recent years. There are

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many types of published drug literature, including efficacy, safety, pharmacokinetic, and pharmacoeconomic studies. It was decided to focus program development on drug efficacy, since practitioners would utilize these studies most frequently and a broad range of concepts could be covered. The institution was initially supportive of the project, and remained so throughout its development.

## Project Description

### Computer Program Development and Timetable

Authorware®, an authoring tool that allows for the development of instructional material incorporating sound, graphics, and animation, was used for the preparation of the program "Evaluation of Clinical Drug Studies" on the Macintosh computer. The first step of the project was initiated in mid-September 1991. A three day Authorware® training program was provided at this time for the project investigators. Following the training, preparation of the content for the "Evaluation of Clinical Drug Studies" program began. The content outline for the computer program included ideas gathered from several books and journal articles (Appendix A). Each investigator was responsible for preparing a draft of the text for different content sections, which were then distributed to the other investigators for review and revision. Consultants' comments were used by the investigators for content and design review and revision. The timetable used for the development and testing of the computer program is found in Appendix B.

### Computer Program Use and Evaluation

During the Spring 1993 semester (January - May), the computer program was used by the second professional year pharmacy students (76 total) in a required 1 credit hour "Introduction to Drug Literature" course. Each week, the students working in groups were assigned a different section of the program to complete on their own. The subject matter was entirely self-contained in the computer program. The program automatically recorded the amount of time that each student/group spent using the computer, and the total amount of time students actually spent using the computer was compiled.

The evaluation of the computer program used a pre-test/post-test design and contrast and study groups of students. During January 1992, a pre-test designed to determine baseline knowledge of drug literature evaluation principles was administered to the class of fourth year pharmacy students who represented the contrast (comparison) group in this project. These students did not receive drug literature evaluation material as part of their formal pharmacy education. This pre-test was very similar in content to the pre-test given later to the study group of students. A post-test, similar in content to that of the pre-test but longer in length, was administered to the contrast group students during their final class in May 1992. Computer program evaluation data were also obtained from the pharmacy students in the expanded 2 credit hour "Introduction to Drug Literature" course taught during the Spring 1994 semester. A pre-test and post-test were also administered to these students, and computer use and attitudinal data were collected.

### Program Revisions and Updates

The program has undergone considerable changes since the time it was first used. Minor changes in program content have been made continuously, based upon student feedback, reviewers' comments, and investigator review. Two entirely new sections were also developed. It was desired for the computer program to ultimately be available for use on two platforms, Macintosh and Windows. The Macintosh fonts were changed to accommodate those commonly used in Windows; the Windows version is now nearly complete.

## Evaluation/Project Results

### Program Evaluation

The pre-test results, post-test results, and attitude survey findings from the contrast and study groups, and the computer use data from the study group, are described in Appendix C. Both the mean and median pre-test scores for the 77 contrast group students who took the exam were 21 out of 50 total points (42%), with a range of 12.5 to 28 points out of 50 (25% to 56%). The mean pre-test score for the study group students was 44%, with a range of 29% - 56%. The mean post-test score for the study group was 77%, with a range of 51% - 97%. This increase was statistically significantly different from both the pre-test score, as well as the contrast group post-test score. The results demonstrated that the computer program was associated with significant learning of the drug study evaluation material by students. This was verified by student attitudes. Students in the Spring 1994 course received an average grade of 42% on the pre-test (median = 43%, range = 24% - 65%), compared to an average of 83% on the post-test (median = 85%, range = 58% - 98%). The increase in post-test scores was again significant and reinforces the program's effectiveness in increasing drug literature evaluation skills.

The study group students spent a mean of approximately 11 hours (range = 4 - 25 hours) using the computer program. The attitudes of the study group students toward use of the computer program are shown in Table VI of Appendix C. Pharmacy students in the "Introduction to Drug Literature" course during the Spring 1994 semester spent 11.1 $\pm$ 5.1 hours (mean $\pm$ SD) using the computer program (median = 10.4 hours, range = 1.2 to 26.1 hours). The mean time is similar to that obtained previously from the study group students. The attitudinal survey results from the Spring 1994 students are shown in Appendix D. Based upon the pre-test and post-test comparisons, as well as student opinion, the program and project as a whole have been deemed to be a success.

### Plans for Continuation and Dissemination

The computer program will continue to be used in the WVU School of Pharmacy's curriculum and will also be incorporated into the School of Medicine's curriculum. Evaluative data will continue to be obtained. To prepare for distribution of the "Evaluation of Clinical Drug Studies" program, copyright registration was obtained in August, 1994. Since the target audience for program use is quite broad, the investigators are considering working with a pharmaceutical manufacturer in its program distribution efforts. Initial discussion and negotiation with a manufacturer, Astra/Merck, is underway. The principal investigator also intends to gain greater proficiency with the use of Authorware Professional® in order to facilitate her work with the computer program.

## Summary and Conclusions

A comprehensive computer instructional program has been developed which can successfully educate students to critically analyze published drug efficacy studies. Before initiating a project such as this, individuals need to be aware of the considerable development time and effort required. This time and effort are not only required for the initial computer program work, but for revision, maintenance and distribution as well.

# Final Report - Main Section

## Project Overview

A computer instructional program was developed to teach health professions students how to critically analyze and interpret published drug efficacy studies. The project was initiated because students at West Virginia University (WVU) did not receive any instruction in this area, and increased computer use at the WVU School of Pharmacy was desired. Also, the content was well-suited for development in a computerized format since the concepts involved were not expected to change rapidly. Thus, program updating would be easier.

An initial version of the computer program, "Evaluation of Clinical Drug Studies," was developed over a 16 month period for use on the Macintosh computer. It was evaluated by second professional year pharmacy students at WVU during two consecutive years (1993 and 1994). The program was found to significantly increase students' knowledge of drug study evaluation concepts and to improve their ability to critically evaluate published efficacy studies, compared to pre-tests and a contrast group of students. In general, students felt that the program was of high quality and useful in increasing their subject knowledge. The major criticisms related to the time involved to complete the program (thought by some to be too much for a 1 or 2 credit hour class), the lack of detailed handout material (remedied to an extent by the development of a fairly comprehensive workbook containing a content outline and learning objectives), and the lack of need for undergraduate pharmacy students to know such material (certain students expressed this concern, even though drug study evaluation skills are deemed to be essential by educators and clinical practitioners nationally).

Overall, the project was shown to be a success. An IBM compatible Windows version of the program is currently being completed. The most appropriate avenue(s) to use for program dissemination are being identified and should be initiated shortly.

## Purpose

The idea to develop a computer instructional program to teach critical evaluation of published drug studies arose due to a number of factors. First, the importance of literature evaluation skills was well known to the investigators, two of whom are drug information specialists. An American Association of Colleges

of Pharmacy (AACP) Background Paper identified the ability to appraise and evaluate clinical drug studies as a skill required of entry-level pharmacy practitioners in order to provide pharmaceutical care. The need for pharmacy and medical students and practitioners to possess these skills was also being widely publicized in a variety of professional journals.

Second, computer assisted instruction was incorporated into pharmacy school curricula to only a limited extent nationwide. However, the flexibility and portability of computer assisted instruction, combined with its student centered learning focus, made it desirable to develop. Third, although a number of checklists, scoring systems and algorithms were published to assist health care providers in evaluating clinical studies, they were generally brief and did not adequately explain the concepts contained. It was anticipated that a computer instructional program would be a useful method for teaching drug literature evaluation techniques, since many examples and levels of explanation could be incorporated into a computer and reviewed by users to the extent desired.

Finally, pharmacy students at WVU received a required one credit hour course in drug literature, but the course focused on texts and not journal articles. This, combined with the investigators' interest in computers and instructional methods, led to the idea of developing a comprehensive computer program to teach the critical analysis of drug efficacy studies.

The program was originally anticipated to serve as a completely self-contained instructional program, i.e., without a need to provide content lectures. In this regard, it has served its purpose reasonably well. However, to help students apply the concepts learned, exercises were developed based upon actual clinical studies. The exercises were useful for determining areas of confusion or misunderstanding in the computer program's content; this allowed for clarification of these areas and the incorporation of additional examples. About 10 - 15 minutes of each weekly class were also allocated for answering student questions about the content, although students did not usually ask questions. This year (1995) in the Introduction to Drug Literature course, four 50 minute class periods were set aside for computer program content clarification and questions/answers. Additional class periods were also used to review the answers to the drug study exercises. The investigators are not convinced, however, about the necessity of this from a student learning perspective. In the future, a self-study exercise set with answer key could be developed for use in conjunction with the computer program.

Pitfalls encountered with the development and use of the computer

program include the following. It required a considerable amount of time to learn how to use Authorware Professional®, more than originally anticipated. Since the investigators had other responsibilities in addition to this project, it was difficult at times to keep on schedule and the principal investigator often had to pick up the workload of others. A principal investigator needs to understand this and be prepared to expend the extra energy required to make a project work. An instructional designer should also be available to anyone who initiates a project such as this. They would be extremely valuable in designing the screen layouts, selecting fonts and colors, and in helping to use software such as Authorware. Adequate time must be allowed to identify the area(s) of the curriculum in which to utilize such a computer program. Although it was anticipated that the program would be used by the medical as well as the pharmacy school, curriculum revision delays in the medical school have slowed the program's introduction into its curriculum. Finally, adequate equipment and private work areas must be available for student use. Some students are distracted by crowds or talking in a computer lab and don't work well under these conditions.

## Background and Origins

Computer assisted instruction was used infrequently at the West Virginia University Schools of Pharmacy and Medicine prior to initiation of this project. Individual schools within the WVU Health Sciences Center had limited resources for the purchase and maintenance of computer equipment, and they had inadequate numbers of machines to accommodate students. The need to increase computer use within the health sciences curricula was recognized, however; the WVU Health Sciences Center began operation of its Computer Based Learning Center (CBLC) in 1991.

Another curricular deficiency noted was that students in the West Virginia University Schools of Pharmacy and Medicine did not receive any formal education in drug literature evaluation techniques. The need for such education has been increasingly called for in recent years, by such groups as educators, practitioners, journal editors, and even the lay public. Thus, the investigators decided to create a project team to develop a computer instructional program that would educate students to critically evaluate the published literature.

There are many types of published drug studies, including efficacy, safety, pharmacokinetic, and pharmacoeconomic studies. It was decided to focus program development on drug efficacy, since practitioners would utilize these studies most frequently and a broad range of concepts could be covered by such a

focus. There was also an existing course in drug literature that was taught by one of the investigators, which would facilitate incorporation of the completed computer program into the pharmacy curriculum. Another investigator is the Associate Dean for Curricular Affairs in the WVU School of Medicine, a position from which program incorporation into the medical school curriculum could be facilitated.

The institution was initially supportive of the project, and remained so throughout its development. A commitment for support was obtained from the CBLC, and the Deans of the Schools of Pharmacy and Medicine. The faculty of the School of Pharmacy was in the process of reviewing aspects of its curriculum at the time of the project's inception and was supportive of a 1 credit hour increase in the introductory drug literature class to incorporate the completed computer program. This credit hour increase was in place for the second test group of pharmacy students. However, incorporating the computer program into the medical school's curriculum has not gone as smoothly. A major problem with the medical curriculum is finding a location for new material; ideally, other information should first be deleted. Planned curricular revisions have also been slower to develop than originally anticipated. When curricular changes are finally initiated, the investigators are optimistic that an appropriate location will be identified for the computer program, most likely during the second year of medical school.

## Project Description

### Computer Program Development and Timetable

Authorware®, an authoring tool that allows for the development of instructional material incorporating sound, graphics, and animation, was used for the preparation of the program "Evaluation of Clinical Drug Studies" on the Macintosh computer. Approval to utilize this software was granted by FIPSE prior to funding of the original application. Key factors influencing the selection of Authorware® included its user-friendliness, the lack of a need for programming skills in order to use the software, and the future availability of Authorware® for Windows, which would allow the program to be fairly readily converted to run on Windows machines after completion of the Macintosh version. The StuffIt™ Installation Technologies software package was used to compress the completed Macintosh program onto floppy disks (due to the size of the program -- currently over 8 MB) and automatically uncompress it later.

The first step of the project initiation began in mid-September 1991. A three-day Authorware® training program was provided at this time for the project investigators by a training and development specialist from the software's manufacturer. During this workshop, the investigators learned the basics of Authorware® operation. Following the training, preparation of the content for the "Evaluation of Clinical Drug Studies" program began. The focus of this program involves teaching health professional students how to critically evaluate published drug efficacy studies. The detailed content outline and learning objectives for each section of the computer program are found in Appendix A - Computer Program Workbook. The first group of pharmacy students to use the computer program, during the Spring 1993 semester, did not have this workbook to use. Rather, these students received a less detailed outline of topics and learning objectives to use in conjunction with the program. The more comprehensive workbook was subsequently prepared in response to the students' comments that such a workbook would be beneficial.

The content outline for the computer program included ideas gathered from several books and journal articles. Each investigator was responsible for preparing a draft of the text for different content sections, which were then distributed to the other investigators for review and revision. The investigators scheduled weekly meetings to facilitate content development and the discussion of changes. During the latter part of 1992, a consultant reviewed the first section of the computer program with respect to its design and interactivity. He provided the investigators with written feedback and suggestions for change. Another consultant later reviewed the statistics section of the program when completed with regard to content; he similarly provided comments and suggestions for change. A third consultant reviewed the complete first version of the computer program during 1993 and also provided written comments and feedback. The materials from all the consultants were used by the investigators for content and design review and revision. To obtain additional computer program design ideas, the investigators reviewed interactive educational software at the National Library of Medicine's Learning Center for Interactive Technology during May 1992.

The timetable used for the development and testing of the computer program is found in Appendix B. Initially, it was planned to have a completed version of the computer program ready by May 1992; however, the extensiveness of the program necessitated that greater development time be spent during year 2. To perform basic functions with Authorware®, such as entering text, setting response types, preparing feedback, and setting up basic screens, the software is fairly straightforward to use. However, when developing many sections,

branching, sound and animation, it becomes more complicated and time-consuming to work with. There is definitely a learning curve that must be navigated to optimally use Authorware®. It is important to allow sufficient time for actual software use and the incorporation of the developed materials. Also, the amount of time needed to adapt the content from written blocks of text to a computer screen format should not be underestimated. An instructional designer, not available to the investigators, would have been of immense benefit in the program's preparation. Also, although it was planned to field test the program from October to December 1992 with selected pharmacy and medical students, this was not possible since development and formatting of the program was still underway. However, a senior pharmacy student assisted with the review and development of the program during the fall semester (September - December, 1992). She completed each section of the program and recorded the time required, prepared written comments related to the program's clarity and format, and helped write content and quiz questions for some of the sections. Version one of the program was completed by January, 1993.

Computer Program Use and Evaluation

During the Spring 1993 semester (January - May), the computer program was used by the second professional year pharmacy students (76 total) in a required 1 credit hour "Introduction to Drug Literature" course. Although the School of Pharmacy faculty had approved an increase in credit hours of the course to accommodate the computer program, the change did not begin for this year's class. Since the computer program was equivalent in content length to at least a 1 credit hour class, the students were essentially asked to complete at least 2 credit hours of coursework for 1 hour of credit. This affected students' use of and opinions regarding the program (described in the "Evaluation/Project Results" section which follows).

Each week, the students working in groups were assigned a different section of the program to complete on their own time. The subject matter was entirely self-contained in the computer program, i.e., class lecture time was not used to present the topics. Lectures were used for the other material traditionally taught in the course. Part of each hour lecture was available to answer any questions students had about their computer program assignment for that week. However, few questions about the computer material were usually raised by the students. To assist students in applying the information learned from the computer program to actual studies, each group of students (26 total groups of two to three students) received a different published drug efficacy study to review. Every other week during the course, the students were given questions

pertaining to their study that required an understanding of the corresponding material in the computer program. The investigators used the students' responses to identify areas in the program requiring clarification, revision, or expansion, and to make appropriate changes. Students were also asked to write down and hand in their comments about each computer program section. The comments were reviewed and the program revised as needed. Some changes made in the program as a result of students' suggestions included the addition of "Previous" and "Next" buttons to each screen of the program. This allowed users to skip material already mastered without first having to complete all interactions on the screen.

The program automatically recorded the amount of time that each student/group spent using the computer. The total amount of time the students actually spent using the computer program was compiled. Also, attitudinal surveys pertaining to each of the individual computer sections and a survey covering the program overall were completed by the students.

The evaluation of the computer program used a pre-test/post-test design and contrast and study groups of students. During January 1992, a pre-test designed to determine baseline knowledge of drug literature evaluation principles was administered to the class of fourth year pharmacy students who represented the contrast (comparison) group in this project. These students did not receive drug literature evaluation material as part of their formal pharmacy education. This pre-test was very similar in content to the pre-test given to the study group of students (who used the finished computer program during year 2 of the project), and included questions pertaining to all aspects of drug efficacy study evaluation principles. The students were also asked questions about an actual drug efficacy study they were instructed to read in advance. A post-test, similar in content to that of the pre-test but longer in length, was administered to the contrast group students during their final class in May, 1992. Since students could not be randomly assigned into the contrast and study groups, demographic data were collected from each group to determine if they were comparable with regard to the following relevant attributes: age, grade point average, previous college degree (if any), subscription to journals, previous coursework in statistics or research methodology, prior exposure to the critical analysis of research studies, and previous participation in research projects.

Although not part of the original project proposal, computer program evaluation data were also obtained from the pharmacy students in the expanded 2 credit hour "Introduction to Drug Literature" course during the Spring 1994 semester. A pre-test and post-test were administered to these students, and

computer use and attitudinal data were collected. The time spent using the computer program was also recorded for the Doctor of Pharmacy degree students who used the program during the Fall 1994 semester.

Originally, it was planned to administer a brief follow-up post-test to the contrast and study group students after the clerkship semester in their final year of school. The follow-up post-test score in the study group was to be compared to the contrast students' scores and used as a measure of the study students' long-term knowledge retention. However, the only time this test could reasonably be administered was at the end of a comprehensive, several hours long post-clerkship examination, since the students are scattered throughout West Virginia during their clerkship semester. The post-test could only be very brief, given the length of the rest of the exam. As a result of this, combined with the fact that students knew it did not count toward their overall clerkship grades, the results were not felt to be meaningful and have not been used.

Program Revisions and Updates

The program has undergone considerable changes since the time it was first used in the Spring of 1993 to present. Shortly prior to the initial testing, the program screens needed to be resized. The CBLC had purchased several new computers with small monitors; a program developed for a larger monitor using Authorware will disproportionately cut off the right and bottom portions of each screen when used on a smaller monitor. Thus, each screen of the program had to be re-formatted. Immediately following use by the first study group, the investigators learned that the primary font used in the program, Chicago, was a poor font for instructional development. The investigators then selected a serif font, Palatino, to substitute and again had to change each individual screen of the program.

Minor changes in program content have been made continuously, based upon student feedback, reviewer's comments, and investigator review. Development of two entirely new sections also began following computer use by the first study group. One was a "Correlation" subsection added to "Statistics." The other, "Program Review," consists of a series of questions for each of the main sections (and subsections) of the computer program; a total of 15 sections of questions (with about 15-25 questions per section) were developed. The program is designed to randomly choose about 10 questions each time the user reviews an individual section. The "Program Review" portion was completed prior to computer program use by the 1995 class. The investigators plan to continue to develop new questions for "Program Review," so that a comprehensive question

bank can be maintained.

From a instructional design perspective, it was also desired for each section or subsection of the computer program to be completed in an average of 30 minutes or less. Based on user data, several sections of the program were found to require significantly more time to complete. The content of these sections ("Journals, Titles, Authors, Abstracts," "Patients/Subjects," "Controls, Design, Randomization, Blinding") was further divided, and submenus were added that allowed for them to be completed in shorter time periods. Four sections/subsections still require over 30 minutes to complete (mean = 37 - 47 minutes); plans are underway to similarly subdivide them.

It was desired for the computer program to ultimately be available for use on two platforms, Macintosh and Windows. During conversion of the program from the Macintosh to a Windows format, the investigators initially used type fonts for Windows that were the same as those used on the Macintosh (e.g., Palatino, New Century Schoolbook, Chicago, etc.). Unfortunately, it was later realized that when the Windows version is "packaged" by Authorware for distribution, the fonts are not automatically included. Since most Windows users do not have Macintosh compatible fonts, the investigators once again needed to change the fonts in the program. This time, the fonts were changed to accommodate those commonly used in Windows, e.g., Times New Roman, Arial, Century Schoolbook). This revision is almost complete.

New sections will continue to be developed for the "Evaluation of Clinical Drug Studies" program, in both platforms. These sections, "Regression" and "Multivariate Analysis" for "Statistics" and a main "Discussion/Conclusions" portion, can be used by advanced level students (e.g., graduate students, Doctor of Pharmacy [Pharm.D.] students) and for nontraditional Pharm.D. program use. Nontraditional programs, to allow current B.S. degree practitioners to obtain a Pharm.D. degree on a part-time, external basis, have been developed by a few schools of pharmacy thus far, and their development is being planned by several others, including WVU.

## Evaluation/Project Results

The pre-test results, post-test results, and attitude survey findings from the contrast and study groups, and the computer use data from the study group, are described in Appendix C -- "Development and Evaluation of a Computer-Assisted Instructional Program to Teach Critical Evaluation of Drug Studies." A

summary of several of these findings follows.

Pre-Test and Post-Test Scores

Both the mean and median pre-test scores for the 77 contrast group students who took the exam were 21 out of 50 total points (42%), with a range of 12.5 to 28 points out of 50 (25% to 56%). Surprisingly (since students knew that the pre-test did not count towards their overall course grade), the majority of students attempted to answer all the questions on the pre-test and appeared to have read the assigned published drug study in preparation for it. Since the contrast group received no instruction in evaluating clinical drug studies, it was anticipated that the post-test grades would not significantly increase (pre-test mean = 42%, post-test mean = 34%). However, the decrease in the mean post-test score compared to the pre-test was unanticipated, i.e., it was expected to at least remain the same. The primary reason for the post-test decline was thought to result from its administration during final exam week. Students were asked to review two published articles in preparation for the post-test; since they knew the test would not count towards their overall course grade (unlike their other finals), it was likely that the students did not thoroughly review the articles. To determine the extent to which this was true, both the pre-tests and post-tests were re-scored without the journal article questions. The revised pre- and post-test scores were in fact similar (mean pre-test score = 43.8%, mean post-test score = 42.2%).

The mean pre-test score for the study group students was 44%, with a range of 29% - 56%. Although the difference between the contrast and study group pre-test scores achieved statistical significance (P=0.04), the two percentage point difference was not believed to be meaningful. The mean post-test score for the study group was 77%, with a range of 51% - 97%. This increase was statistically significantly different from both the pre-test score, as well as the contrast group post-test score. The results demonstrated that the computer program was associated with significant learning of the drug study evaluation material by students. This was verified by student attitudes, in which only 3% of students felt that they already knew most of the information in the program and 85% felt that they learned new information.

Students in the Spring 1994 course received an average grade of 42% on the pre-test (median = 43%, range = 24% - 65%), compared to an average of 83% on the post-test (median = 85%, range = 58% - 98%). The increase in post-test scores is significant and reinforces the program's effectiveness in increasing students' drug literature evaluation skills. Similar to the study group students,

only 4% of the Spring 1994 group felt they already knew most of the information in the program, and 84% believed they learned new information.

Computer Use Time and Attitudes - Study Group

The study group students spent a mean of approximately 11 hours (range = 4 - 25 hours) using the computer program. The attitudes of the study group students toward use of the computer program are shown in Table VI of Appendix C. The primary complaint with regard to the program was the amount of time required to complete it, with the second most frequent complaint being the lack of handouts or a workbook to use in conjunction with the program. Another complaint of several students related to a lack of appreciation of the need to know how to critically analyze and interpret published drug studies. Unfortunately, this problem is unlikely to be resolved until changes are accomplished in the entire curriculum. The study group students had limited pharmacy practice experience at the time they took the "Introduction to Drug Literature" course, and the curriculum did not require them to retrieve and review published drug studies until their final year (and even then, to only a limited extent). However, this situation should be remedied by two major curricular changes, one in progress and the other planned. First, problem-based learning (PBL) is being implemented in our pharmacy curriculum as a result of a current FIPSE grant. This is currently affecting our first professional year pharmacy students. PBL requires greater use of supplemental information resources (beyond course lecture notes). Second, plans are underway for conversion to a six year entry-level pharmacy curriculum, with significantly greater emphasis on clinical expertise and practice-based experience. The ability to critically evaluate the literature will be readily apparent to students in such a curriculum.

Computer Use Time and Attitudes - 1994 Data

Pharmacy students in the "Introduction to Drug Literature" course during the Spring 1994 semester spent 11.1 $\pm$ 5.1 hours (mean $\pm$ SD) using the computer program (median = 10.4 hours, range = 1.2 to 26.1 hours). The Doctor of Pharmacy degree students (six total) in the Fall 1994 semester spent an average of 11.5 hours using the program (range = 8.4 to 17.8 hours). The mean times are similar to those obtained from the study group students; thus, the program length has been fairly accurately determined.

The attitudinal survey results from the Spring 1994 students are shown in Appendix D. The findings are comparable to the previous year, with the most common complaint still being the amount of time required. However, the

computer program workbook, a new addition, was considered to be helpful by 63% of respondents. Several students expressed a desire to simply receive handouts and attend lectures rather use the computer program. This is not surprising, considering that the vast majority of the pharmacy curriculum consists of lectures and exams which test rote memorization of material. Also, expansions scheduled for the CBLC, used by the students to view the computer program, have been delayed. Thus, it was often crowded and some students indicated difficulty in working there.

Success of Project

Based upon the pre-test and post-test comparisons, as well as student opinion, the program and project as a whole have been deemed to be a success. Further, in 1993 the investigators submitted the computer program and a portfolio of project-related work to AACP for consideration to receive one of their "Innovations in Teaching" awards. Our project was one of the three selected as winners. As a winner, $1200 was awarded to travel to San Diego to present (in both a poster and platform format) the results from this project. The program was demonstrated later that year at the American Association of Medical Colleges annual meeting as well as the SCAMC (Symposium on Computer Applications in Medical Care) meeting. As a result of these presentations, and others within West Virginia, individuals from at least 30 different institutions (including three pharmaceutical manufacturers) have expressed interest in receiving a copy of the program.

Plans for Continuation and Dissemination

The computer program will continue to be used in the WVU School of Pharmacy's curriculum and will also be incorporated into the School of Medicine's curriculum. Evaluative data will continue to be obtained from students using the program to assist with future revision efforts.

To prepare for distribution of the "Evaluation of Clinical Drug Studies" program, copyright registration was obtained in August, 1994. Rather than simply distributing the program to those who expressed an interest in it, the investigators have been working on a distribution mechanism by which the costs (diskettes, time, mailing, etc.) can not only be recovered, but a small amount of additional money obtained to allow for continued program revision. The investigators are also interested in reaching a variety of different audiences with the program: students in several health professions, pharmacy and medicine residents, educators, health care practitioners, journal editors and reviewers, and

pharmaceutical industry personnel. Since the target audience is quite broad, the investigators are considering working with a pharmaceutical manufacturer in its program distribution efforts.

An educational liaison for the pharmaceutical manufacturer Astra/Merck viewed the computer program a few months ago and, as a result, provided the investigators with a $5000 unrestricted educational grant to continue work on the project. The investigators are using this money to begin to develop a condensed, practitioner's version of the computer program. This version will focus on the most important questions to ask when reviewing a published drug study and will be able to be completed within a shorter time period. It is envisioned that the program could be used in a stand-alone manner or as a supplement to the detailed version. In March 1995, the educational liaison and three other individuals from Astra/Merck headquarters visited WVU for the purpose of discussing areas of mutual interest involving the computer program. The meeting was productive and several future directions for program development were considered. Astra/Merck should be contacting the investigators shortly with a specific proposal for collaboration. If they do not wish to become involved with distributing the current program, the investigators are pursuing a working arrangement with the Health Sciences Consortium for program distribution to educational institutions.

A colleague in the WVU School of Pharmacy is interested in expanding the material presented in the "Evaluation of Clinical Drug Studies" program to include the critical evaluation of pharmacokinetics studies. In this regard, a brief proposal was submitted for funding to the Drug Information Association (DIA) for the development of an "Evaluation of Pharmacokinetic Drug Studies" program. This program, when completed, could be used in a stand-alone manner or in conjunction with the current program. Preliminary interest in funding the proposal has been expressed by the DIA, and its president, Dr. Louis A. Morris of the Food and Drug Administration (FDA), has asked to receive a copy of the current "Evaluation of Clinical Drug Studies" program to review. Dr. Morris has asked for the IBM Windows version, which should be completed and sent within the next two weeks. If Dr. Morris is favorably impressed by the program, the opportunities for its use within government agencies and throughout pharmaceutical industry should be enhanced. Also, if the proposal is funded by the DIA, they have already requested that both the current program and the developed "Evaluation of Pharmacokinetic Drug Studies" program be demonstrated at the DIA Annual Meeting in June, 1996.

The principal investigator also intends to gain greater proficiency with the

use of Authorware Professional® in order to facilitate her work with the computer program. A new version of Authorware Professional® (Macintosh and Windows) is due to be released in April 1995. The principal investigator plans to attend a three day Authorware advanced training workshop in June 1995 as part of her development efforts in this regard.

## Summary and Conclusions

The investigators have truly enjoyed their involvement with this project. A comprehensive computer instructional program has been developed which can successfully educate students to critically analyze published drug efficacy studies. Further, in the process of completing the project, the investigators have learned a great deal more about instructional design, computer assisted instruction, and the implementation of new educational strategies. The principal investigator in particular has also become relatively proficient in the use of a powerful software development program, Authorware Professional®. As a result of this undertaking, the investigators can envision other types of computer instructional projects that would be of value to develop, especially as curriculum revisions are planned both in the Schools of Pharmacy and Medicine at WVU, and throughout the nation.

Before initiating a project such as this, individuals need to be aware of the considerable development time and effort required. This time and effort are not only required for the initial computer program work (including content preparation, formatting, programming, and testing), but for revision, maintenance and distribution as well. Working with different computer platforms and equipment (similar to those which a variety of users might possess) produces unique challenges that must be anticipated and overcome. Program records and documentation are also important to maintain throughout the project. Finally, the topic(s) for which computer instructional materials are developed should be well-suited for this media. The satisfaction of having developed a program that one is proud of, however, can compensate for the extraordinary effort expended for it.

# Appendix B

## Timetable for Project

### Year 1

| Date | Activity |
|---|---|
| September, 1991 | Authorware training |
| September, 1991 - August, 1992 | Database development, field testing |
| January - May, 1992 | Pre-test and post-test administered to contrast group of pharmacy students (in their 4th year of the curriculum) |

### Year 2

| Date | Activity |
|---|---|
| September, 1992 | Database development (continued) |
| September, 1992 - May, 1993 | Collect data concerning knowledge of drug literature evaluation techniques a second time from the contrast group of pharmacy students (in their 5th year of the curriculum) |
| October - December, 1992 | Pilot testing of database by selected students |
| November - December, 1992 | Revision and refinement of database |
| January - May, 1993 | Pre-test and post-test administered and database evaluated using study group of pharmacy students (in their 4th year of the curriculum) |
| June - August, 1993 | Data analysis and interpretation |

### Year 3

| Date | Activity |
|---|---|
| September, 1993 - May, 1994 | Collect data concerning knowledge of drug literature evaluation techniques a second time from the study group of pharmacy students (now in their 5th year of the curriculum) |
| June - August, 1994 | Final data analysis and interpretation |

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Appendix C

# Development and Evaluation of a Computer-Assisted Instructional Program to Teach Critical Evaluation of Drug Studies[1,2]

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## INTRODUCTION

Computer-assisted instruction (CAI) has been used in medical education for several years, although its development continues to exist in an evolutionary stage(1,2). CAI has also been incorporated into various subject areas in the pharmacy curriculum(3-7), but to a relatively limited extent. Educators in both pharmacy and medicine have been encouraged to continue to utilize and exploit the full potential of computers in the curriculum(1,8).

The education of students in the techniques of critical appraisal of drug studies has been identified as a deficiency in many health sciences curricula(9,10). Errors in research

[1] Supported by grant P116B10076 from the U.S. Department of Education, Fund for the Improvement of Postsecondary Education (FIPSE).

[2] Presented by Marie Abate in part during the Innovations in Teaching Award poster and platform sessions, AACP Annual Meeting, July 1993, San Diego, CA.



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design and inconsistencies in the reporting of study results exist in professional pharmacy and medical journals, despite the presence of editorial boards and the peer-review process(11,12). Therefore, thorough and accurate interpretation of the primary literature is essential for assuring that patients receive appropriate drug therapy. Health care educators have reported that students must know how to critically analyze drug studies and understand statistical methods in order to interpret such studies(11,13,14). A recent AACP background paper has identified the ability to appraise and evaluate clinical drug studies as a skill required of entry-level pharmacy practitioners in order to provide pharmaceutical care(15).

Several checklists, scoring systems, and algorithms have been published to assist health care providers in evaluating clinical studies(16-18). It was anticipated that a CAI program would also be a useful method for teaching students how to critique published drug studies, since numerous examples and levels of explanation could be incorporated into a computer and accessed and reviewed by users to the extent desired. In addition, a program of this type would promote active learning by students. The objective of our project was to develop and evaluate a comprehensive CAI program which would educate students to evaluate all aspects of published drug efficacy studies thoroughly and critically.

## METHODS

**Program Development.** Authorware Professional® (Macromedia, San Francisco, CA) was used for development of the computer instructional program, initially on the Macintosh platform. This software allows for the development of instructional material which incorporates sound, graphics, and animation, without the need for programming expertise by the developer. In addition, it allows for conversion of the program to a PC Windows environment. An Authorware® training program which provides an overview of the basic operation of the software was offered by the manufacturer and attended by the investigators.

Development of the instructional program began in September, 1991. An outline of topics to be covered in the program with corresponding learning objectives (Appendix A) was prepared. The goal was to develop a self-contained, stand alone, interactive CAI program that would educate students to critically analyze and evaluate all aspects of published drug studies, with a focus on drug efficacy. For example, in the area of statistics, students would be expected to understand statistical concepts, not to actually compute statistics tests. Since the material in the program had not been taught previously, the content first needed to be outlined and text prepared. The CAI program was intended to replace lectures and included instruction, examples, questions, responses, and feedback, as well as sound, graphics, plus the ability for students to receive remediation or continue to progress through the program. Content development and formatting of the material into an interactive design continued from September, 1991 until September, 1992. Initial refinement of the program by the investigators prior to its formal evaluation occurred from September to December, 1992. A senior pharmacy student also reviewed the program in detail during this period, prepared written comments/suggestions related to its clarity and format, and recorded the time required for the completion of each computer section.

**Program Evaluation.** The evaluation plan utilized a pretest/posttest design with control and test groups of pharmacy students. The control or contrast group consisted of the 77 second professional year pharmacy (BS degree) students enrolled in a required one credit hour Introduction to Drug Literature (IDL) course in the spring semester of 1992. This group received no instruction in critical drug study evaluation techniques, since undergraduate pharmacy students at West Virginia University had not received required formal instruction in this area prior to development of the computer program. Therefore, the control group served to measure the exposure of students to any drug study evaluation concepts received during other courses. The control group was administered a pretest, designed to determine their understanding of important characteristics of clinical drug studies and their ability to analyze and evaluate such studies, at the beginning of the IDL course. The pretest consisted of multiple choice and short essay type questions, part of which pertained to an actual published drug efficacy study. Cognitive skills and not simply factual recall were tested by many of the questions. Examples of the pretest and posttest questions are provided in Appendix B. A posttest similar in content and design to the pretest, with the exception of additional questions pertaining to two published efficacy studies, was administered at the end of the course.

The test group consisted of the 76 second professional year pharmacy students enrolled in the IDL course during the spring semester of 1993. Demographic and other pertinent background data were obtained from both the control and test groups to determine if they differed significantly with regard to important attributes. At the start of the IDL course, the test group was administered a pretest almost identical to that completed by the control group the previous year. The computer program was designed to be very user friendly and a simple knowledge of Macintosh basics, *e.g.*, clicking and dragging, was sufficient for its use. The class was divided into smaller groups and given 30 minutes of hands-on introduction to the use of the Macintosh computer and how to access the drug study evaluation program. Basic Macintosh operation tutorials were also available on the computers for students to review on their own, if desired. The program was installed on 14 Macintosh IIci or si computers in the Health Sciences Center's Computer Based Learning Center (CBLC) for student use throughout the semester at any time the lab was open, weekdays or weekends.

The students were then divided into groups of two or three each and assigned to review one to two sections/subsections of the program every two weeks during the semester. However, students were allowed to review the program individually if computer space was available. Due to an inability at that time to increase the credit hours of the IDL course to accommodate the greater workload, the computer assignments represented additional effort for the class; this was explained to students at the beginning of the course. Students were given a copy of the learning objectives and a topical outline to use while viewing the program. Each student group was also given a different published clinical drug efficacy study to review. Six exercises assigned throughout the semester asked questions which related to the clinical study and which evaluated students' comprehension of the instructional program's contents. In addition, the exercises alerted the investigators to content areas in the computer program which might have been incomplete or un-

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**Table I. Program content outline**

| | |
|---|---|
| Section 1 - | Clinical Literature and Types of Studies |
| Section 2 - | Introduction/Background |
| Section 3 - | Journals, Titles, Authors, Abstracts |
| Section 4 - | Patients/Subjects |
| Section 5 - | Controls, Design, Randomization, Blinding |
| Section 6 - | Treatment Considerations |
| | Drug Considerations |
| | Study Settings |
| | Patient Factors |
| Section 7 - | Measurements |
| Section 8 - | Statistics |
| | Variables, Data, and Distributions |
| | Measures of Central Tendency |
| | Measures of Variability |
| | Statistical Inference |
| | Parametric Tests |
| | Nonparametric Tests |
| Section 9 - | Data Handling |

clear. Students were asked to maintain a "log" of problems/comments/suggestions that arose while reviewing the program.

Surveys designed to determine student attitudes toward the computer program overall and toward its different sections were administered four times during the semester. The surveys consisted of a series of statements which students were asked to rank using a 5 point Likert-type scale (*i.e.*, 5 = strongly agree, 1 = strongly disagree). The final survey also asked students to expand upon those statements which they rated positively or negatively. The computer automatically recorded the amount of time which the students/groups spent using the program and the total computer time was compiled for each student. The program allowed the investigators to determine whether or not an individual section or subsection of the program was accessed, although it was not possible to obtain an accurate time breakdown for each section due to the program's design, *i.e.*, the freedom of students to move from one section to another during a session.

A posttest containing questions almost identical to those given to the control group was administered to the test group students at the end of the semester. Student *t*-tests or ANOVA were performed to compare the pretest and posttest scores between the control and test groups. Paired *t*-tests were used to determine the differences between the pretest and posttest scores within the control and test groups. An alpha level of 0.05 was considered the cut-off for determining statistical significance. Cronbach's coefficient alpha method was used to evaluate the internal reliability of the attitudinal survey items(19).

## RESULTS

**Program Preparation, Content and Use.** The instructional program developed, entitled "Evaluation of Clinical Drug Studies," consisted of nine main sections, two of which contained several subsections. A total of 16 separate sections and subsections were prepared. Since the computer material was developed to stand alone, only 15 to 20 minutes per week of classroom lecture time were allotted for program discussion, primarily to answer any content-related questions from students. The content outline of the program is shown in Table I. The entire program utilized approximately 6 MB of disk space and print-outs of the computer screens have filled four large ring binders. Although students were divided into small groups to facilitate access to the CBLC computers, slightly more than half of the students (53 percent) indicated that they preferred to work alone instead of in a group. The majority of students (87 percent) felt they received sufficient initial instruction as to how to access and use the program.

It was difficult to determine the total amount of preparation time required for the initial version of the instructional program, given the number of investigators involved in its development, the often part-time nature of their work on the program, and the time spent reading, reviewing, and revising each prepared section. Although Authorware® was designed to be user friendly, there was still a considerable learning curve which needed to be overcome in order to use it optimally. In addition, a problem arose midway through the development of the program when the CBLC bought additional Macintosh computers with a smaller monitor size than those already present in the lab. To allow the program to run on the smaller monitor, each screen of information had to be re-sized individually, which added several hours to the preparation time and resulted in two versions of the program (*i.e.*, one small screen and one full screen) being maintained and operated at the same time. The investigators felt that approximately 15 hours would be necessary in order for users to cover thoroughly all the material and examples presented in the computer program. All totaled, it is estimated that up to 50 hours were spent for the program's preparation for each hour of material developed.

The students spent a total of $10.9 \pm 4.4$ hours (mean $\pm$ SD) reviewing the instructional program (minimum time = 4.0 hours, maximum time = 25.0 hours, median time = 9.9 hours). However, as shown in Table II, a total of 49 students (64 percent) skipped at least one section/subsection of the program, with 32 percent skipping three or more sections/subsections and nine percent missing over half of the program. This was consistent with the primary complaint of the students with regard to the program, *i.e.*, the amount of time required for only a one credit hour course (see **"Attitude Assessment"**). Two students specifically stated that they did not have the time to spend on the program given the rest of their workload and simply stopped reviewing the sections.

**Pretest and Posttest Scores.** Relevant background data pertaining to the control and test groups of students are shown in Table III. The control and test groups had virtually identical ages and mean professional program GPAs. Slightly more control students had prior experience with statistics or research methods than those in the test group. This might have been expected to result in better performance on the pretest by those in the control group, although this did not occur.

The pretest and posttest scores from both the control and test group students are shown in Table IV. The difference between the control and test group pretest means barely achieved statistical significance, with a two percentage point difference. However, a significant increase in the posttest compared to the pretest scores occurred only in the test group students, demonstrating that the computer program significantly improved the students' knowledge of critical drug study evaluation techniques and their ability to evaluate primary literature.



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**Table II. Sections/subsections skipped**

| Number of sections/ subsections skipped | Number (percent) of students |
|---|---|
| 1 - 2 | 25 (32.9) |
| 3 - 5 | 13 (17.1) |
| 6 - 8 | 4 ( 5.3) |
| 9 - 11 | 7 ( 9.2) |

**Table III. Background data from control and test groups**

| Characteristic | Group | |
|---|---|---|
| | Control | Test |
| Males | 18 | 23 |
| Females | 59 | 53 |
| GPA[a] | 3.28 ± 0.36 | 3.29 ± 0.38 |
| Age (yrs) | 23 ± 3 | 22 ± 3 |
| Percent with previous stat. course | 18.7 | 14.5 |
| Percent with previous research methods course | 12.0 | 5.3 |
| Percent with prior degree | 12.0 | 10.7 |

[a] Upon entrance into IDL course.

much time being required to complete the program and the lack of a detailed handout/workbook to use. Students were informed the first day of the IDL course about the extra work expected from them in order to complete the computer program assignments, beyond that normally associated with the course. Several students specifically commented on their attitudinal survey that they did not receive enough credit for the work in the course. Related to the time requirement, the second most frequent complaint from students was that they had to take too many notes while reviewing the computer program and many asked to receive accompanying handout material or a workbook.

Several students provided written comments other than those pertaining to the time commitment and handouts. Some students felt that pharmacists did not need to know how to evaluate journal articles, as illustrated by the following statements: "This class is Drug Literature—not evaluating drug studies and it is my belief that this type of knowledge is not useful to the common BS RPh," "In the 'typical' pharmacy in community practice you will not be reading study articles. You will read things like *American Pharmacy* [sic] or *Drug Topics* . . .I do feel this course is important for physicians," and "This class should be an elective for someone who wants to go into research." Other students commented: "I like learning on my own!!," "Only improvement is to make it available for home use," and "I enjoyed the computer learning type of setup."

**Table IV. Pretest and posttest percent grades**

| Student group | Pretest mean ± SD | Range | Posttest mean ± SD | Range |
|---|---|---|---|---|
| Control | 41.6 ± 3.2[a,c] | 26 - 56 | 33.9 ± 7.0[c] | 15 - 50 |
| Test | 43.6 ± 3.1[a,b] | 29 - 56 | 77.4 ± 9.3[b] | 51 - 97 |

[a] $P=0.04$; [b] $P=0.0001$; [c] $P=0.0001$.

**Table V. Computer time spent by students receiving lowest and highest posttest grades**

| Posttest grade (N) | Time (hrs) using program | |
|---|---|---|
| | Mean | Range |
| 50 - 59% (5) | 6.9 | 6.0 - 7.9 |
| 90 - 99% (6) | 17.4 | 10.6 - 25.0 |

An analysis of the total time spent by students reviewing the computer program *vs.* the posttest scores found a relatively weak correlation overall between these two variables (r=0.44). However, a considerable difference existed between the time spent using the computer program by the students with the lowest vs. the highest scores on the posttest, as shown in Table V. The students who received a score of 90 percent or better on the posttest spent on average slightly over 10 hours more time reviewing the computer program than those with the lowest scores. As expected, the students with a posttest score of 90 percent or better skipped fewer (mean = 1; 0 to 3) sections/subsections of the program, compared to those with the lowest scores (mean = 5; 1 to 10 sections/subsections skipped).

**Attitude Assessment.** A coefficient alpha reliability measure of 0.93 was calculated for the attitudinal survey items. A summary of the final attitudinal survey which assessed the students' overall opinions of the computer program is shown in Table VI. The major negative comments involved too

Students were also asked whether they would like to see the use of more, less, or the same amount of various computer program features such as sound, moving objects, or narration. These features had been incorporated into the program to varying extents. The students indicated they would prefer less answers that needed to be typed in (44 percent of respondents) and less need to drag responses on the screen (55 percent), but more animation of objects (41 percent), more audio narration (41 percent), and more sound effects (47 percent).

## DISCUSSION AND CONCLUSIONS

Educators have clearly stated that need exists for pharmacy students and practitioners to evaluate clinical studies critically and to understand and analyze research design(15,20). A combination of factors led the investigators to develop a CAI program which would teach students these skills: the desire to enhance the students' ability to think critically and solve problems; the desire to develop course materials which promote active student learning; the need to promote greater flexibility in the curriculum and to develop programs which could be used at remote off-campus sites; the desire to develop instructional methodologies which would ultimately release faculty time for other activities; and the lack of availability of any existing CAI programs in this area. Sev-



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**Table VI. Overall attitudinal survey results**

| Statement | Mean | Frequencies (Percent) | | |
|---|---|---|---|---|
| | | Strongly agree to agree (5,4) | Neutral (3) | Disagree to strongly disagree (2,1) |
| 1. Already knew most of information in program | 1.9 | 2.7 | 5.4 | 91.9 |
| 2. Learned new information from program | 4.1 | 85.1 | 9.5 | 5.4 |
| 3. Learned useful and relevant information from computer program | 3.4 | 55.4 | 25.7 | 18.9 |
| 4. Pharmacists need to know how to evaluate and interpret journal articles | 3.6 | 64.8 | 16.2 | 19.0 |
| 5. Liked the way screens designed and information presented | 3.7 | 68.9 | 18.9 | 12.2 |
| 6. Liked colors used | 4.0 | 83.8 | 9.4 | 6.8 |
| 7. Difficult to understand the material presented in program | 2.7 | 24.3 | 23.0 | 52.7 |
| 8. Information in program geared to appropriate level | 3.5 | 65.8 | 17.8 | 16.4 |
| 9. Using computer program was interesting | 3.2 | 51.4 | 20.8 | 27.8 |
| 10. Took too long to complete sections[a] | 4.1 | 81.0 | 9.0 | 10.0 |
| 11. Prefer to work alone on computer | 3.3 | 53.5 | 11.3 | 35.2 |
| 12. Would prefer to use computer to learn material than attend lectures | 3.1 | 41.7 | 19.4 | 38.9 |
| 13. Overall, quality of program was high | 3.5 | 62.2 | 20.2 | 17.6 |
| 14. A major deficiency of program was lack of detailed handout/workbook | 4.1 | 79.7 | 6.8 | 13.5 |
| 15. Programs of this type are valuable educational tools | 3.3 | 53.5 | 11.3 | 35.2 |

[a] Combined results from first three attitudinal surveys.

eral reports in the pharmacy literature have shown the effectiveness of CAI in various subject areas, generally when compared to traditional lectures(3,6). However, a recent review of CAI research concluded that enhanced effectiveness and efficiency of this modality relative to other forms of instruction has not been established(2).

In our study, since the control group received no instruction in drug literature evaluation techniques, it was not possible to compare the program's effectiveness to a traditional lecture format. However, the "Evaluation of Clinical Drug Studies" program was shown to significantly increase students' drug efficacy study evaluation knowledge and skills. Since the time requirement for the IDL course with the computer component was excessive for one credit hour, a significant number of students skipped sections of the program. It is anticipated that student posttest scores and therefore knowledge of the subject will further improve as a result of curricular changes to be implemented at the school of pharmacy during the spring semester of 1994; *i.e.*, an increase in credit hours of the IDL course from one to two to accommodate the computer program, together with less required credit hours overall that semester.

In the control group students, the mean posttest score actually decreased in comparison to the pretest score, which was unanticipated, *i.e.*, it was expected to remain stable. The primary reason for the posttest score decline was thought to result from its administration during final exam week. The students were asked to read and review two published articles in preparation for the posttest. Since they knew the test would not count towards their overall course grade (unlike their other finals), it was highly probable that the students did not thoroughly review their articles. To determine the extent to which this was true, both the pretests and posttests were re-scored without the journal article related questions. The revised pre- and posttest scores were in fact similar (mean pretest score = 43.8 percent, mean posttest score = 42.2 percent).

Despite the complaints from several students that they did not receive enough credit for their work in the IDL course, students generally agreed that they liked the program's screen design and way in which the information was presented. They reported that they learned new information from the program, the information was geared to the appropriate level, and the overall quality was high. The students were almost equally divided as to whether they preferred to use the computer to learn the material or attend lectures. Other studies have shown that while pharmacy students would like to see CAI used for portions of courses, the majority did not desire an entire course to be given via computer, or for the computer to completely replace lectures(4,5). With an increase in credit hours of the IDL course beginning in 1994, the intention is to allow students one hour per week of class time for use of the computer program. This should provide students with adequate time to complete all sections of the computer program, which should then translate into an even greater improvement in posttest scores. Portions of the remaining classes will be used for small group discussions of published efficacy studies and to review the course exercises pertaining to drug studies. In this way, material covered in the computer program can be reinforced by actual contact time during class.

Future plans for the "Evaluation of Clinical Drug Stud-



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ies" program include the addition of regression analysis information and a section describing the analysis of the Conclusion/Discussion portion of a published study, development of a DOS Windows version, the incorporation of greater amounts of sound and animation, the addition of more examples for students to review as desired, and the preparation of an accompanying workbook. Version 2.0 of the program will be distributed to interested schools and colleges in late 1993. It is also planned for the program to be used in the postbaccalaureate doctor of pharmacy degree curriculum, the medical school curriculum, by practitioners for continuing education, and at off-campus sites, and for sections of the program to be used in other courses in the pharmacy curriculum. It is important that comprehensive, time intensive CAI programs be adaptable for use in multiple ways. This will assure that the development and maintenance costs of such endeavors will be appropriately compensated.

In summary, the "Evaluation of Clinical Drug Studies" program was a unique and successful addition to the pharmacy school curriculum. The development and evaluation of similar programs in different content areas should continue to be explored.

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## APPENDIX A. LEARNING OBJECTIVES

As a result of completing the computer program, the participant should be able to:

1. **Section 1—Clinical Literature and Types of Studies**
   a. Know the two basic types of medical research studies.
   b. Describe the format of the four observational studies (descriptive [case-series], case-control, cross-sectional, cohort) and *recognize* their advantages and disadvantages.
   c. Describe experimental studies and briefly discuss their advantages and disadvantages.
2. **Section 2—Journals, Titles, Authors, Abstracts**
   a. *Recognize* what the goals of a journal should include.
   b. Describe what a journal citation is and its significance.
   c. Describe the reason that advertising is included in a journal and its effect, if any, on quality.
   d. Discuss the purpose and functions of an editorial board and its members.
   e. Describe the peer review process and its purpose.
   f. Discuss the potential conflicts of interest for authors of a published study.
   g. Describe the purpose of the abstract of a published article.
3. **Section 3—Introduction/Background**
   a. List the four points which the Introduction/Background section of a published study should include.
   b. Describe the two types of hypotheses.
   c. Identify whether an alternative hypothesis is one-tailed (sided) or two-tailed (sided).
   d. Restate (as necessary) the objective of a study in the form of a null hypothesis.
   e. Determine whether or not a study's objective is appropriately stated.
4. **Section 4—Patients/Subjects**
   a. Describe what the inclusion criteria and the exclusion criteria refer to in a study.
   b. Discuss the importance of the inclusion and exclusion criteria in regard to a study's results and their interpretation.
   c. Describe how a homogeneous or heterogeneous sample can affect the interpretation of a study's results.
   d. Briefly describe the types of random sampling and indicate why it is preferred over nonrandom sampling.
   e. Describe selection bias and how it could be minimized in a study.
   f. Describe the meaning of "informed consent" and its importance.



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g. Indicate *when* the investigators should determine the number of subjects which they should include in their study.

**5. Section 5—Controls, Design, Randomization, Blinding**

a. Explain why controls are important to utilize in a study.
b. Describe the types of controls which exist.
c. Indicate the type(s) of controls which would allow one to truly determine whether a study drug itself has any efficacy.
d. Describe the concurrent control (parallel treatment), "before and after" (time series), and cross-over study designs.
e. *Recognize* the advantages and disadvantages of each type of study design.
f. Describe the meaning of a "carry-over effect" and how it can be minimized.
g. Briefly describe random assignment and its advantages.
h. Discuss the types, and importance, of blinding in a study.
i. Discuss how "unblinding" could occur in a study.

**6. Section 6 —Treatment Considerations**

**Drug Considerations Subsection**

a. Briefly describe the following points in an efficacy study:
   1. Related to dosage considerations:
      1) relationship between dose and response
      2) whether potency implies a therapeutic advantage
      3) potential problems with fixed doses
      4) importance of therapeutic ranges
      5) active control dosage
      6) equivalency of dosage range
   2. Related to dosage form considerations:
      1) convenience/ease of administration
      2) absorption/bioavailability
      3) time to achieve therapeutic concentrations
   3. Related to dosage regimen considerations:
      1) timing in relation to food
      2) timing during day
      3) duration of administration
   4. Related to drug concentrations:
      1) when drug concentrations should be monitored
      2) steady-state concentrations
   5. Related to concurrent medication:
      1) interaction with study drug(s)
      2) effect on disease state
      3) amount taken
   6. Related to adverse effects:
      1) reporting of cause and effect relationship (memorization of definitions is *not* required)
      2) determination of intensity

**Study Site or Setting Subsection**

a. Indicate whether studies performed using patients in one type of setting can be extrapolated to another type.
b. Differentiate the study features/factors which are characteristic of inpatient vs. outpatient settings.
c. Briefly describe the primary use for artificial study settings.

**Patient Factors Subsection**

a. Briefly summarize the importance of examining the inclusion and exclusion criteria in a study.
b. Discuss the importance of the risk-to-benefit ratio when analyzing efficacy studies.
c. Briefly indicate how disease severity can affect compliance.
d. Briefly describe whether patient compliance is a concern in clinical studies and whether it would be a greater problem with inpatients or outpatients.
e. Explain the meaning and significance of compliance bias.
f. *Recognize* the different methods for assessing compliance and indicate the best way to measure and assess compliance in a study.
g. Briefly describe the intent-to-treat and exclusion of subjects approaches to analyzing data which includes noncompliant patients.

**7. Section 7—Measurements**

a. Briefly describe random error and systematic error and what can be done to minimize each type.
b. Explain the meaning of validity and differentiate between internal and external validity.
c. Describe the meaning of reliability, sensitivity, and specificity.
d. Discuss the importance of evaluating whether false positive or false negative results occurred in a study.
e. Indicate when the endpoints used for efficacy measurement should be identified or selected for a study.
f. Describe the four points to consider when evaluating whether the measures of outcome used in a study are appropriate.
g. Briefly discuss what the Hawthorne effect refers to.

**8. Section 8—Statistics**

**Subsection 1—Variables, Data and Distributions**

a. Differentiate between the dependent and independent variables in a clinical study.
b. Describe nominal, ordinal, and continuous scales (levels) of measurement.
c. Explain what a histogram is and what it is used for.
d. Describe a normal distribution, an asymmetric distribution, and the terms for data distributions with two or more peaks.

**Subsection 2—Measures of Central Tendency**

a. Describe the mean and the level(s) of data for which it can be appropriately used.
b. Describe the median and the level(s) of data for which it can be appropriately used.
c. Discuss whether the mean and median values can be significantly affected by outlying data points.
d. Describe the mode and the level(s) of data for which it can be appropriately used.
e. For each of the following data distributions, describe the relationship between the mean, median, and mode:
   1) Normal distribution
   2) Symmetrical distribution with two peaks
   3) Asymmetric distribution with one peak
   4) Asymmetric and bimodal distribution

**Subsection 3—Measures of Variability**

a. Explain the meaning of the range and whether it can be affected by outlying data.
b. Describe standard deviation, the types of data it is used for, and the % of data points included in the mean $\pm$ 1 SD, the mean $\pm$ 2 SD, and the mean $\pm$ 3 SD.
c. Describe how the size of the SD influences the spread of data points around the mean.
d. Define the term variance.
e. Describe the standard error of the mean and its relationship to the SD.
f. Discuss the meaning of the confidence interval.
g. Describe how the width of the CI varies depending on:
   1) the level of confidence selected, e.g., 90% CI vs. 95% CI vs. 99% CI
   2) the SD of the study sample
   3) the sample size (i.e., size of study group)
h. For each level (scale) of measurement, indicate whether the SD, SEM, and CI can be appropriately used to describe it.



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**Subsection 4—Statistical Inference**

a. Differentiate between a population and a sample, and a parameter and a statistic.
b. Describe the purpose of hypothesis testing and statistical inference.
c. Explain the difference between Type I and Type II errors during hypothesis testing.
d. Describe what the terms alpha and beta refer to in regard to error, and indicate the usual numerical cut-off for an acceptable level of alpha and beta in clinical studies.
e. Describe how Type II error can be minimized in a study.
f. Describe the meaning of a probability (P) value and its normal cut-off for concluding that statistical significance exists.
g. Describe how a P value larger than the normal cut-off would be interpreted.
h. Discuss the meaning of statistical power and indicate how it is mathematically defined.
i. Describe three factors which affect the power of a statistical test.
j. Indicate when it would be appropriate to use one-tailed vs. two-tailed statistical tests.
k. Indicate whether P values or confidence intervals reveal the *size* of differences between study groups.
l. Differentiate between clinical and statistical significance in a study.

**Subsection 5—Parametric Tests**

a. Describe the differences between the assumptions necessary for the use of parametric tests vs. nonparametric tests.
b. Describe the purpose of a *t*-test and differentiate between paired and nonpaired *t*-tests.
c. Determine whether a t-test reported in a clinical study was appropriately used.
d. Describe the problem with the use of multiple t-tests for comparisons between more than two groups.
e. Describe the purpose of an ANOVA procedure and the assumptions which apply for its use.
f. Determine whether an ANOVA procedure reported in a clinical study was appropriately used.
g. Describe the meaning of an F-ratio from an ANOVA procedure.
h. Discuss when it would be appropriate to use a one-way ANOVA, a two-way ANOVA, and a repeated measures ANOVA.
i. Recognize the types of multiple comparison procedures and explain the purpose for their use.

**Subsection 6—Nonparametric Tests**

a. Describe when it is appropriate to use nonparametric tests.
b. Indicate the level of data for which it is appropriate to use the Chi-Square test, Fisher's exact test, McNemar test, and Rows by Columns test.
c. Briefly explain the theory behind the Chi-Square test.
d. List the assumptions necessary for the use of the Chi-Square test.
e. Briefly explain when the Fisher's exact test should be used instead of the Chi-Square test.
f. Describe when it would be appropriate to use the McNemar test.
g. Briefly indicate when and why a corrected Chi-Square test (Yate's correction) is used.
h. Describe when it would be appropriate to use the Mann-Whitney U (Wilcoxon rank-sum) test.
i. Describe when it would be appropriate to use the Wilcoxon signed-rank test.
j. Discuss when it would be appropriate to use the Kruskal-Wallis test, and indicate the parametric test which would be its counterpart.
k. Discuss when it would be appropriate to use the Friedman test, and indicate the parametric test which would be its counterpart.

**Subsection 7—Correlation**

a. Describe the purpose of performing a correlation analysis.
b. Discuss the correlation coefficient (r) in regard to its range of values and interpretation.
c. Identify two methods used to calculate correlation coefficients and briefly differentiate between the criteria for their appropriate use.
d. Discuss how large an r value should be to provide a meaningful result.
e. Describe how to predict the variability in one measurement which can be accounted for by the other in a correlation analysis.
f. Describe whether or not correlations can be tested for statistical significance.
g. Explain whether a statistically significant r implies that a strong or important correlation exists.

**9. Section 9—Data Handling**

a. Describe the significance of patient drop-outs from a study.
b. Discuss the advantages and disadvantages of two methods used for the analysis of data, the intent-to-treat and the exclusion of subjects methods.
c. Explain how investigators should handle drop-outs in their published studies.
d. Explain whether or not missing data points are a significant problem in a clinical study.
e. Discuss why it is important for a description of variability to be included with any summary data.
f. Describe the significance of a small vs. large SD in a dataset.
g. Describe two major points to consider when evaluating the outcome data reported in a study.
h. Briefly describe four characteristics which tables and graphs in a published study should have.
i. Indicate how one should ideally include the zero point in a graph that has many data points of large value.
j. Indicate a circumstance in which percentages can be misleading.
k. Discuss whether a reported percent change in a value is useful by itself in a study.
l. Describe what to look for when determining whether statistical tests or procedures were appropriately used in a study.

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## APPENDIX B. QUESTIONS FROM PRETEST AND POSTTEST

1. In a study to determine whether beta-agonists increased the risk of near death in patients with asthma, 150 patients who had a near-fatal asthma episode within the previous two years and 200 patients without such an episode were selected. Patients' records were examined to determine their drug use. Beta-agonists were used twice as frequently in the patients who had a near-fatal asthma episode. This study is best described as a:
   a. controlled experiment
   b. cohort study
   c. descriptive study
   d. case-control study
   e. cross-sectional study
2. Explain in your own words the meaning of power as indicated in this sentence from pg. 166 of the article you were given to read, "Statistically, it was determined that 23 subjects would



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be needed to detect a difference between the treatments with a power of 90 and a level of significance of .10."

3. Briefly describe why a nonparametric test was utilized for the intensity rating scale (*i.e.*, rating of the severity of the reactions) data.

4. a. Describe what a Type I error refers to.
   b. What is another term for a Type I error level?

5. A study reports that a statistically significant difference exists between two antihypertensive agents. Does this imply that clinical significance also exists? Explain.

6. Which type of blinding is preferred for drug efficacy studies?
   a. Unblinded
   b. Single-blind
   c. Double-blind
   d. All are equally appropriate

7. In a study comparing the effectiveness of clonidine to propranolol for the treatment of mild hypertension, half of the patients are randomized to receive clonidine first, and the other half propranolol. After two months, the patients receiving clonidine are given propranolol and those receiving propranolol are given clonidine.
   The type of design used in this study is:
   a. "before and after" or time series
   b. concurrent control or parallel treatment
   c. cross-over

8. Based on the results from the study you were given to read, would it be appropriate to conclude that any smoker would significantly benefit from use of the transdermal patch? Explain.

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# Appendix D

## Computer Program Evaluation Summary
## Additional Year of Evaluation - 1994

Rating scale used: **5** = Strongly agree, **4** = Agree, **3** = Neutral, **2** = Disagree, **1** = Strongly disagree

1. Appropriate number of topics covered in computer program
   **5, 4** = 54 students, **3** = 9 students, **2, 1** = 11 students

2. Already knew most of information in computer program
   **5, 4** = 3 students, **3** = 2 students, **2, 1** = 70 students

3. Examples in computer program helped me understand information
   **5, 4** = 56 students, **3** = 12 students, **2,1** = 7 students

4. Learned new information from the computer program
   **5, 4** = 63 students, **3** = 6 students, **2, 1** = 6 students

5. Learned useful and relevant information*
   **5, 4** = 33 students, **3** = 21 students, **2,1** = 21 students

6. Liked colors used in program
   **5, 4** = 56 students, **3** = 15 students, **2, 1** = 4 students

7. Liked screen design and way information presented
   **5, 4** = 54 students, **3** = 18 students, **2, 1** = 3 students

8. Difficult to understand material in computer program*
   **5, 4** = 27 students, **3** = 19 students, **2, 1** = 29 students

9. Computer program workbook was helpful
   **5, 4** = 47 students, **3** = 15 students, **2, 1** = 13 students

10. Appropriate amount of time allocated for computer program*
    **5, 4** = 18 students, **3** = 10 students, **2, 1** = 47 students

11. Program improved ability to read and evaluate published drug studies
    **5, 4** = 47 students, **3** = 16 students, **2, 1** = 12 students

12. Information in program geared to appropriate level
    **5, 4** = 47 students, **3** = 14 students, **2, 1** = 14 students

13. Prefer to use computer rather than attend lectures*
    **5, 4** = 26 students, **3** = 15 students, **2, 1** = 33 students

14. Overall quality of program was high
    **5, 4** = 44 students, **3** = 23 students, **2, 1** = 8 students

* The most frequent complaint was that the course still required too much time for a 2 credit hour class; Also - several students disliked having to spend a great deal of time in the computer based learning center using the program, and preferred to simply attend a lecture and receive handout materials; some students did not feel that a pharmacist needs to know how to evaluate drug studies (although it is clear to educators nationwide that this skill is not only important, but a specific objective of the newly proposed 6 year entry level pharmacy degree program); some students expressed difficulty in understanding some of the computer program material, especially the statistics sections (almost all students had no statistics background prior to this course).



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## Appendix E

### Information for FIPSE

The investigators found the FIPSE staff and program officers to be extremely helpful in all aspects of the project. They were available to answer any questions, and always did so in a timely manner. When mistakes were made on the budget (and there were some!), our program officer Dr. David Johnson was polite, tolerant and informative. He worked with us to resolve problems. Of the various granting agencies that the investigators have dealt with in the past, FIPSE was truly unique with regard to the efforts expended to work with the investigators. The annual project directors' meeting is an excellent idea that needs to be continued. These meetings were a true learning experience. It was very beneficial for the various project directors to speak with each other, share common educational experiences (across a variety of diverse disciplines), and learn what each other is doing.

We feel that FIPSE should continue to provide funding consideration for computer based education projects such as ours. How these types of materials can be used optimally in the curriculum is an area that still needs to be fully explored. Also, distance learning and nontraditional programs (i.e., off-campus, part-time) are emerging areas of interest in the medical professions. The optimal use of the computer as a learning tool in these environments should be studied.

Finally, we wish to personally thank the FIPSE staff for their support of our idea and our program officers (Dr. Eulalia Cobb initially, followed by Dr. David Johnson) for helping us to make it a reality. It is appreciated.